JAN 2 2 2002

K012480

# 510(k) Summary of Safety & Effectiveness

**Submitter**

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

**Contact**

Mr. Mike Sammon, Ph.D.
Director, Research and Development
(863) 683-8680, extension 228
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**Date**

July 27, 2001

**Device**

- Trade Names: Vanguard Reprocessed Inflation Devices
  - ⇒ ACS Indeflator™ Inflation Devices
  - ⇒ Medtronic Everest™ 20/30 Inflation Devices
  - ⇒ Merit Medical Systems Monarch™/ IntelliSystem®25 Inflation Devices
  - ⇒ SCIMED® Encore® 26 Inflation Devices
- Common Name: Inflation device or syringe
- Classification: Class II – Syringe, Balloon Inflation
- Product Code MAV

**Predicate Devices**

Respective ACS, Medtronic, Merit Medical, and SCIMED® legally marketed inflation devices under various 510(k) premarket notifications.

**Indications for Use**

The inflation device is designed to inflate and deflate an angioplasty balloon or other interventional device and to monitor pressure within the balloon.

*Continued on next page*

Indeflator is a trademark of Advanced Cardiovascular Systems, Inc.
Everest is a trademark of Medtronic, Inc.
Monarch and IntelliSystem are trademarks of Merit Medical Systems, Inc.
SCIMED and Encore are registered trademarks of Boston Scientific Scimed, Inc.

# 510(k) Summary of Safety & Effectiveness, Continued

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| **Device Description** | An inflation device is designed to generate and monitor pressure and is used in angioplasty or other interventional procedures. It is a sterile hand-held mechanical device comprised of a 20 cc syringe, pressure gauge, plunger, connector tube and a male luer fitting for connection to a catheter. The device may be used in conjunction with other accessories such as a hemostatic valve or stopcock, guide wire introducer or torque device.<br><br>Vanguard receives previously used inflation devices from healthcare facilities; cleans, inspects, tests, repackages and sterilizes the devices; and returns them to the healthcare facility. |
| **Technological Characteristics** | The Vanguard reprocessed inflation devices are essentially identical to the currently marketed OEM devices. No changes are made to the currently marketed device's specifications and they possess the same technological characteristics. Biocompatibility and performance/functional testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use. |
| **Test Data** | Sterilization and packaging validations, and functional/performance, and biocompatibility testing demonstrates that the reprocessed devices perform as intended and are safe and effective. |
| **Conclusion** | Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard reprocessed inflation devices are substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2002

Mike Sammon, Ph.D.
Director, Research and Development
Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

Re: K012480
Vanguard Reprocessed Inflation Devices
Regulation Number: 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: 74 MAV
Dated: November 25, 2001
Received: November 27, 2001

Dear Dr. Sammon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with

all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number: K012480

Device Name: Vanguard Reprocessed Inflation Devices

Indications for Use:

The inflation device is designed to inflate and deflate an angioplasty balloon or other interventional device and to monitor pressure within the balloon.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012480